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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,284	04/09/2004	Bradley Moore	DEP5292	1111

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EXAMINER	
HOFFMAN, MARY C	
ART UNIT	**PAPER NUMBER**
3733	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,284	MOORE ET AL.	
	Examiner	Art Unit	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 30-36* is/are pending in the application.

4a) Of the above claim(s) *34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/16/2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagliuca et al. (2003/0073998) in view of Chin (2005/0065517, see Provisional Application 60518580).

Pagliuca et al. disclose a minimally invasive surgical method comprising making a first incision in a patient; expanding the first incision to create a first pathway from the first incision to a first vertebra and a second vertebra;

advancing a first anchor through the pathway to a first anchor site on the first vertebra; advancing a second anchor through the pathway to a second anchor site on the second vertebra (see FIG. 90); implanting a third anchor (anchors: ref. #'s 4604), positioning a first end of a fixation element in the first pathway; and coupling the fixation element (ref. #4650) to the first anchor, the second anchor, and the third anchor. Expanding the first incision includes dilating the first incision to the first and second vertebrae. Dilating the first incision comprises sequentially dilating the first incision to the first and second vertebrae (paragraph [0191], FIG 33). Expanding the first incision further includes inserting a cannula (ref. #1022) into the dilated first incision, the cannula defining the

first pathway from the first incision to the first and second vertebrae, wherein expanding the first incision further includes inserting a retractor (ref. #1024) into the dilated first incision and expanding the retractor within the first incision, the retractor the defining the first pathway from the first incision to the first and second vertebrae. The retractor includes a retractor blade having an opening (ref. #1058) formed therein that is configured to allow the first end of the fixation element to pass therethrough. The first, second, and third bone anchors are polyaxial bone screws (FIG. 86). The fixation element is a spinal rod (FIG. 90). Disk material is removed from the disk space between the first and second vertebrae through the first pathway, the method further comprising inserting bone graft into the disk space, the method further comprising inserting an interbody fusion device into the disk space (FIG. 70, claim 14).

Pagliuca et al. disclose the claimed invention except for making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device having an opening to facilitate coupling to the fixation element, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the fixation element subcutaneously/subfascially to the third anchor; and advancing a closure mechanism through the lumen of the percutaneous access device and engaging the closure mechanism to the third bone anchor to couple the fixation element to the third bone anchor, and further comprising a second fixation element, and a fourth, fifth, and a sixth anchor.

Chin discloses making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device having an opening to facilitate coupling to the fixation element, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the fixation element subcutaneously/subfascially to the third anchor; and advancing a closure mechanism through the lumen of the percutaneous access device and engaging the closure mechanism to the third bone anchor to couple the fixation element to the third bone anchor to perform minimally invasive surgery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Pagliuca et al. making a percutaneous incision in the patient; creating a second pathway to the third vertebra by dilating the incision and inserting a cannula/percutaneous access device (see FIGS. 2a-b) having an opening to facilitate coupling to the fixation element, advancing a third anchor through the percutaneous incision to a third anchor site on the third vertebra; advancing the first end of the fixation element subcutaneously/subfascially to the third anchor (See FIG. 9); and advancing a closure mechanism through the lumen of the percutaneous access device and engaging the closure mechanism (e.g. ref. #164) to the third bone anchor to couple the fixation element to the third bone anchor in view of Chin to perform minimally invasive surgery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Pagliuca in view of Chin using a second

fixation element, and a fourth, fifth, and a sixth anchor, since it has been held that mere duplication involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pagliuca et al. (2003/0073998) in view of Chin (2005/0065517, see Provisional Application 60518580) further in view of Nguyen et al. (2004/0215190).

Pagliuca et al. in view of Chin disclose the claimed invention except for the first end of the spinal rod being bullet-shaped.

Nguyen et al. disclose the first end of the spinal rod being bullet-shaped to facilitate navigation through the tissue (paragraph [0112]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Pagliuca et al. in view of Chin with the first end of the spinal rod being bullet-shaped in view of Nguyen to facilitate navigation through the tissue.

Response to Arguments

Applicant's arguments filed 10/16/2007 have been fully considered but they are not persuasive.

Applicant argues that the examiner provides "no rationale" for combining the Pagliuca et al. and Chin references. Applicant states that the examiner's rationale provided in the rejection (i.e. that it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Pagliuca et al. in

view of Chin to perform minimally invasive surgery) is a mere conclusory statement without a rational underpinning to support the conclusion. The examiner respectfully disagrees with Applicant's assertions. It is well known in the surgical field that minimally invasive surgery has benefits over invasive surgery, such as faster healing times, shorter hospital stays, less risk of infection, less scarring, and less pain. Minimally invasive surgery is a known improvement over invasive surgery made possible by the increased availability of small-sized surgical visualization equipment. One of ordinary skill in the art would know of the benefits associated with minimally invasive surgery and would understand why the use of minimally invasive surgery is a proper rationale for combining the methods of Pagliuca et al. and Chin.

Applicant also argues that the Chin reference, which discloses minimally invasive methods, teaches away from the Pagliuca et al. because Pagliuca et al. discloses invasive methods utilizing a type of expandable access. Again, minimally invasive surgery is an improvement over invasive methods with many known benefits attached. Many surgeries formerly performed invasively are now performed using minimally invasive techniques because of these benefits. The examiner does not understand why Applicant thinks that a method disclosing minimally invasive methods "teaches away" from a method using more invasive methods, since minimally invasive surgery is a known improvement to invasive surgery.

Thus, the rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER